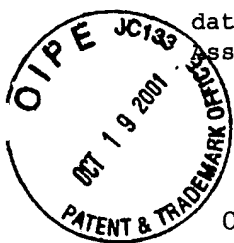


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I hereby certify that this paper and the documents referred to as attached therein are being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

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Denise Ortega

Name

October 17, 2001

Date

Denise Ortega

Signature

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Jan Zavada et al.

Serial No.: 09/967,237

Group Art Unit:

Filed : September 27, 2001

Examiner:

For : MN Gene and Protein

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR SECTIONS 1.56, 1.97 AND 1.98

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The accompanying PTO Form 1449 is submitted pursuant to 37 CFR Sections 1.56, 1.97 and 1.98, directing Applicants to submit literature and information that may be considered material to the examination of the claims of an application. Applicants respectfully submit that this Information Disclosure Statement (IDS) should be considered in accordance with 37 CFR Section 1.97(b)(1), as it is being submitted within three months of the filing date of the subject application, and that no fee is

required for its consideration. However, should any fees be determined to be necessary in connection with this paper, Applicants respectfully request that any such fees be charged to Deposit Account No. 12-0615.

Applicants respectfully point out that the Uemura et al. 1997 abstract, a copy of which is enclosed, states in its first paragraph: "Sequence analysis and database searching revealed that G250 antigen is identical to MN, a human tumor-associated antigen identified in cervical carcinoma (Pastorek et al., 1994)."

Applicants respectfully point out that the "filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in Section 1.56(b)" [37 CFR Section 1.97(h)]; and that an information disclosure statement filed in accordance with 37 CFR Section 1.97 "shall not be construed as a representation that a search has been made." [37 CFR Section 1.97(g)]

Further the identification of any document herein is not intended to be, and, Applicants respectfully submit, should not be construed as being, an admission that such a document, in fact, constitutes "prior art" within the meaning of the applicable laws, since, for example, a given document may have a

later effective date than at first seems apparent, or the document may have an effective date which can be antedated. Applicants respectfully conclude on this point that the "prior art" status of any document is a matter to be resolved during prosecution.

Thus, Applicants respectfully conclude that the citation of references herein is not intended to be an admission that any of the references are considered to be material or to constitute prior art, or that any of the references, either alone or in combination with any other references, would be sufficient to render any of the claims of the above-identified patent application unpatentable.

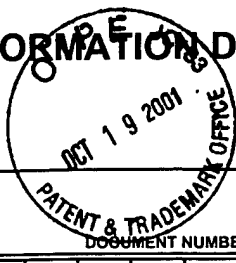
Respectfully submitted

A handwritten signature in black ink, appearing to read 'Leona L. Lauder', is written over the typed name.

Leona L. Lauder  
Attorney for Applicant  
Registration No. 30,863

Dated: October 17, 2001

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APPLICANT

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## U.S. PATENT DOCUMENTS

EXAM. INITIAL	DOCUMENT NUMBER							DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	5	3	8	7	6	7	6	02/07/95	Zavada et al.		536	23.5
	5	5	8	5	4	7	9	12/17/96	Hoke et al.		536	24.5

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO	
	9	5	3	4	6	5	0	12/21/95	WO	C12N 15/12 C07K 14/82, C12N 1/21, 15/62, C12Q 1/68, A61K 39/00, C12N 5/16, C07K 16/18, C12N 15/87, G01N 33/50, A61K 48/00			
	9	3	1	8	1	5	2	09/16/93	WO	C12N 15/33, 1/20, 5/10 A61K 39/12, C12N 15/62 C12P 21/08, A16K39/395 G01N 33/569			
	8	8	0	8	8	5	4	11/17/88	WO	C07K 15/00, A61K 49/02 G01N 33/574, A61K 39/395 C12P 21/00//C12N 15/00 C12N 5/00 (C12P 21:00 C12R 1:91)			

## OTHER DISCLOSURES

	Anton et al., "Localized renal-cell carcinoma: detection of abnormal cells in peritumoral tissue. A cytophotometry and immunocytochemistry study," <u>World J. Urol.</u> , 13(3): 149-152 (1995).
	Bander et al., "Renal cancer imaging with monoclonal antibody G250," <u>J. Urol.</u> , 155 (5 Suppl.): 583A (Abstract 1088) (1996)
EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

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SERIAL NO.

09/967,237

## INFORMATION DISCLOSURE STATEMENT

APPLICANT

Zavada et al.

FILING DATE

September 27, 2001

GROUP

## OTHER DISCLOSURES

1. Zavada et al., "A Study of Biomarkers in Cervical Carcinoma and Clinical Correlation of the Novel Biomarker MN," Gynecologic Oncology, 63: 337-344 (1996)

Costa et al., "MN Protein Immunolocalization in Uterine Cervix Carcinoma With Glandular Differentiation - A Clinicopathologic Study of a New Cancer-specific Biomarker," International Journal of Surgical Pathology, 3(2): 73-82 (1995)

Costa, M., "MN and Ki67 (MIB-1) in Uterine Cervix Carcinoma: Novel Biomarkers With Divergent Utility," Human Pathology, 27(3): 217-219 (March 1996)

Cote, "Protein Antigen Helps Identify Early Cervical Abnormalities," Women's Health Weekly: News Section, p. 7 (March 30, 1998)

Divgi et al., "Scintigraphy of Renal Cell Carcinoma with I-131 Labelled Monoclonal Antibody (MAB) G250," European Journal of Nuclear Medicine, 19(8): 578 (Abstract 121-3) (August 23, 1992)

Divgi et al., "Radioimmunotherapy (RIT) with I-131 Monoclonal Antibody (Mab) G250 in Metastatic Renal Cancer," Proceedings of the 41st Annual Meeting, 35(5): 101P (Abstract #401) (May 1994)

Divgi et al., "Radioimmunotherapy with I-131-G250 in Metastatic Renal Cell Cancer (RCC)," J. Nucl. Med., 36 (5 Suppl.): 913P (Abstract 956; May 1995)

Frohman et al., "Rapid production of full-length cDNAs from rare transcripts: Amplification using a single gene-specific oligonucleotide primer," PNAS (USA), 85: 8998-9002 (December 1988)

Frosch et al., "Cloning and characterisation of an immunodominant major surface antigen of Echinococcus multilocularis," Molecular and Biochemical Parasitology, 48: 121-130 (1991)

EXAMINER

DATE CONSIDERED

ATTY. DOCKET NO.  
D-0021.502SERIAL NO.  
09/967,237

## INFORMATION DISCLOSURE STATEMENT

APPLICANT  
Zavada et al.FILING DATE  
September 27, 2001

GROUP

OCT 19 2001  
PATENT & TRADEMARK OFFICE

## OTHER DISCLOSURES

et al., "Down-regulation of transmembrane carbonic anhydrases in renal cell carcinoma cell lines by wild-type von Hippel-Lindau transgenes," PNAS (USA) 95: 12596-12601 (October 1998)

Karttunen et al., "Colorectal Tumors Show Abnormal Expression of MN/CA IX," Pathology Research and Practice 193/5-6: 392 Abstract No. P198 (Abstract from European Congress on Pathology at Maastricht; August 31 - September 4, 1997)

Kranenborg et al., "Development and Characterization of Anti-Renal Cell Carcinoma X Antichelate Bispecific Monoclonal Antibodies for Two-Phase Targeting of Renal Cell Carcinoma," Cancer Res., 55 (23 Suppl.) 5864s-5867s (1995)

Kurth et al., "Characterization of Human Renal Cell Carcinoma Tumor Lines by Means of Monoclonal Antibodies," Prostate, 6(4): 451 (Abstract) (1985)

Liao et al., "Identification of the MN Antigen as a Diagnostic Biomarker of Cervical Intraepithelial Squamous and Glandular Neoplasia and Cervical Carcinomas," American Journal of Pathology, 145(3): 598-609 (September 1994)

Liao and Stanbridge, "Expression of the MN Antigen in Cervical Papanicolaou Smears Is an Early Diagnostic Biomarker of Cervical Dysplasia," Cancer Epidemiology, Biomarkers & Prevention, 5: 549-557 (July 1996)

Liao et al., "Identification of the MN/CA9 Protein As a Reliable Diagnostic Biomarker of Clear Cell Carcinoma of the Kidney," Cancer Research, 57: 2827-2831 (July 15, 1997)

Luiten et al., "Target-Specific Activation of Mast Cells by Immunoglobulin E Reactive with a Renal Cell Carcinoma-Associated Antigen," Laboratory Investigation, 74(2): 467-475 (1996)

Luiten et al., "Generation of chimeric bispecific G250/anti-CD3 monoclonal antibody, a tool to combat renal cell carcinoma," British Journal of Cancer, 74(5): 735-744 (1996)

EXAMINER

DATE CONSIDERED

ATTY. DOCKET NO.

D-0021.5

SERIAL NO.

09/967,237

## INFORMATION DISCLOSURE STATEMENT

APPLICANT

Zavada et al.

FILING DATE

September 27, 2001

GROUP

## OTHER DISCLOSURES

Lund et al., "Monoclonal Antibodies to Kidney and Tumor-associated Surface Antigens of Human Renal Cell Carcinoma," Cancer Res., 46(11): 5816-5820 (1986)

McKiernan et al., "Expression of the Tumor-associated Gene MN: A Potential Biomarker for Human Renal Cell Carcinoma," Cancer Research, 57: 2362-2365 (June 15, 1997)

Moon et al., "A Highly Restricted Antigen for Renal Cell Carcinoma Defined by a Monoclonal Antibody," Hybridoma, 4(2): 163-172 (1985)

Nakagawa et al., "MN as a Potential Target in Renal Cell Carcinoma," J. Urology, 159 (5 Suppl.): 187, Abstract 720 (May 1998)

Oosterwijk and Debruyne, "Radiolabeled monoclonal antibody G250 in renal-cell carcinoma," World Journal of Urology, 13: 186-190 (1995)

Oosterwijk et al., "The Expression of Renal Antigens in Renal Cell Carcinoma," World Journal of Urology, 2(2): 156-158 (1984)

Oosterwijk et al., "Monoclonal Antibodies that Discriminate Between Renal Cell Carcinomas (RCC) and Other Malignancies," Prostate, 6(4): 451-452 (Abstract) (1985)

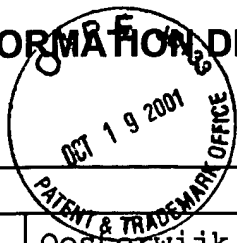
Oosterwijk et al., "Immunohistochemical Analysis of Monoclonal Antibodies to Renal Antigens -- Application in the Diagnosis of Renal Cell Carcinoma," American Journal of Pathology, 123(2): 301-309 (May 1986)

Oosterwijk et al., "Monoclonal Antibody G250 Recognizes a Determinant Present in Renal-Cell Carcinoma and Absent from Normal Kidney," Int. J. Cancer, 38: 489-494 (1986)

EXAMINER

DATE CONSIDERED

# INFORMATION DISCLOSURE STATEMENT


 ATTY. DOCKET NO.  
D-0021.5B-2

 SERIAL NO.  
09/967,237

 APPLICANT  
Zavada et al.

 FILING DATE  
September 27, 2001

GROUP

## OTHER DISCLOSURES

	Oosterwijk et al., "Relationship between DNA Ploidy, Antigen Expression and Survival in Renal Cell Carcinoma," <u>Int. J. Cancer</u> , <u>42</u> : 703-708 (1988)
	Oosterwijk et al., "Expression of Intermediate-sized Filaments in Developing and Adult Human Kidney and Renal Cell Carcinoma," <u>The Journal of Histochemistry and Cytochemistry</u> , <u>38</u> (3): 385-392 (1990)
	Oosterwijk et al., "Antibody Localization in Human Renal Cell Carcinoma: A Phase I Study of Monoclonal Antibody G250," <u>Journal of Clinical Oncology</u> , <u>11</u> (4): 738-750 (April 1993)
	Oosterwijk et al., "The Use of Monoclonal Antibody G250 in the Therapy of Renal-Cell Carcinoma," <u>Seminars in Oncology</u> , <u>22</u> (1): 34-41 (February 1995)
	Oosterwijk et al., "Molecular characterization of the Renal Cell Carcinoma-associated antigen G250," <u>Proceedings of the American Association for Cancer Research</u> , <u>37</u> : 461 (Abstract #3147) (March 1996)
	Oosterwijk et al., "Molecular Characterization of the Renal Cell Carcinoma-Associated Antigen G250," <u>J. Urol.</u> , <u>155</u> : 925 (May 1996)
	Opavsky et al., "Regulation of MN Expression," <u>Cell Biology International</u> , <u>18</u> (5): Abstract No. Mo-58 (1994)
	Opavsky et al., "Human MN/CA9 Gene a Novel Member of the Carbonic Anhydrase Family: Structure and Exon to Protein Domain Relationships," <u>Genomics</u> , <u>33</u> : 480-487 (1996)
	Pastorek et al., "The Structure and Expression of MN Gene, Coding for a Tumor-Associated Protein p54/58N," <u>J. Cancer Res., Clin. Oncol.</u> , <u>119</u> (Suppl. 1) 10/113 (1993)
EXAMINER	DATE CONSIDERED

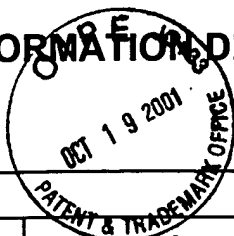


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## INFORMATION DISCLOSURE STATEMENT

APPLICANT  
Zavada et al.FILING DATE  
September 27, 2001

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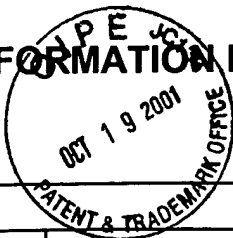


## OTHER DISCLOSURES

\	Pastorek et al., "Cloning and characterization of MN, a human tumor-associated protein with a domain homologous to carbonic anhydrase and a putative helix-loop-helix DNA binding segment," <u>Oncogene</u> , 9: 2877-2888 (1994)
\	Pastorek et al., "MN - A Novel Type of Oncoprotein," <u>Cell Biology International</u> , 18(5): Abstract No. Mo-57 (1994)
\	Pastorekova et al., "A Novel Quasi-viral Agent, MaTU, Is a Two-Component System," <u>Virology</u> , 187: 620-626 (1992)
\	Pastorekova et al., "Transformation of Mammalian Cells by MN Oncogene," <u>Cell Biology International</u> , 18(5): Abstract No. Mo-56 (1994)
\	Pastorekova et al., "MN/CA IX, a Carbonic Anhydrase Isoenzyme Implicated in Carcinogenesis," Abstract submitted to International Conference on Experimental and Clinical Oncology, Greece (October 3-5, 1996)
\	Pastorekova et al., "Carbonic Anhydrase IX, MN/CA IX: Analysis of Stomach Complementary DNA Sequence and Expression in Human and Rat Alimentary Tracts," <u>Gastroenterology</u> , 112: 398-408 (1997)
\	Resnick et al., "Viral and Histopathologic Correlates of MN and MIB-1 Expression in Cervical Intraepithelial Neoplasia," <u>Human Pathology</u> , 27(3): 234-239 (March 1996)
\	Reuters News Report, "Biomarker Resolves Ambiguous Pap Smears" (March 26, 1998)
\	Saarnio et al., "Distribution of carbonic anhydrase isoenzymes I, II, IV, V, VI and MN/CA IX in the human intestine. An immunohistochemical study," Abstract submitted to the meeting for United European Gastroenterological Week, Paris (November 2-6, 1996)
EXAMINER	DATE CONSIDERED

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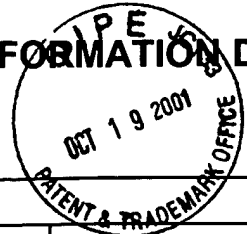
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Zavada et al.

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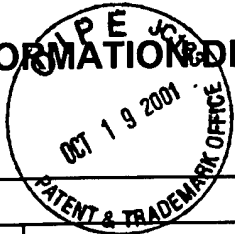
## OTHER DISCLOSURES

	Saarnio et al., "Expression of a Novel Carbonic Anhydrase Isoenzyme, MN/CA IX, In Gallbladder and Hepatitic Tumours," <u>Gut</u> , 41(3): PA186-A186 (1997)
	Saarnio et al., "Immunohistochemistry of Carbonic Anhydrase Isozyme IX (MN/CA IX) in Human Gut Reveals Polarized Expression in the Epithelial Cells with the Highest Proliferative Capacity," <u>Journal of Histochemistry &amp; Cytochemistry</u> 46(4): 497-504 (1998)
	Saarnio et al., "Immunohistochemical Study of Colorectal Tumors for Expression of a Novel Transmembrane Carbonic Anhydrase, MN/CA IX, with Potential Value as a Marker of Cell Proliferation," <u>American Journal of Pathology</u> , 153(1): 279-285 (July 1998)
	Stanbridge, E., "Cervical marker can help resolve ambiguous Pap smears," <u>Diagnostics Intelligence</u> , 10(5): 11 (1998)
	Steffens et al., "Radioimmunotargeting with I <sup>131</sup> labeled chimeric G250 monoclonal antibody in patients with renal cell carcinoma," <u>J. Nucl. Med.</u> , 37 (5 Suppl.): 169P (1996)
	Steffens et al., "Targeting of Renal Cell Carcinoma with Iodine-131-Labeled Chimeric Monoclonal Antibody G250," <u>Journal of Clinical Oncology</u> , 15(4): 1529-1537 (April 1997)
	Steffens et al., "Radioimmunotherapy with <sup>131</sup> I-cG250 Monoclonal antibody in Patients with Metastasized RCC, Phase I/II Study," <u>J. Urology</u> , 159 (5 Suppl.): Abstract 562 (May 1998)
	Surfus et al., "Anti-Renal-Cell Carcinoma Chimeric Antibody G250 Facilitates Antibody-Dependent Cellular Cytotoxicity with In Vitro and In Vivo Interleukin-2-Activated Effectors," <u>Journal of Immunotherapy</u> 19(3): 184-191 (1996)
	Surfus et al., "Renal Cell Human-Mouse Chimeric Antibody G250 Mediates Antibody Dependent Cellular Cytotoxicity (ADCC)," <u>Biological Abstracts</u> , 47(9): 161224 (Abstract 3922) (1995)
EXAMINER	DATE CONSIDERED

	ATTY. D CKET NO. D-0021.502	SERIAL NO. 09/967,237
	APPLICANT Zavada et al.	
	FILING DATE September 27, 2001	GROUP

## OTHER DISCLOSURES

	Turner et al., "MN Antigen Expression in Normal, Preneoplastic, and Neoplastic Esophagus: a Clinicopathological Study of a New Cancer-Associated Biomarker," <u>Hum. Pathol.</u> , 28(6): 740-744 (June 1997)
	Tweedie and Edwards, "Mouse Carbonic Anhydrase III: Nucleotide Sequence and Expression Studies," <u>Biochemical Genetics</u> , 27(1/2): 17-30 (1989)
	Uemura et al., "Internal Image Anti-Idiotypic Antibodies Related to Renal-Cell Carcinoma-Associated Antigen G250," <u>Int. J. Cancer</u> , 56: 609-614 (1994)
	Uemura et al., "Vaccination with Anti-Idiotypic Antibodies Mimicking a Renal Cell Carcinoma-Associated Antigen Induces Tumor Immunity," <u>Int. J. Cancer</u> , 58: 555-561 (1994)
	Uemura et al., "Immunization with Anti-Idiotypic Monoclonal Antibodies Bearing the Internal Image of the Renal-Cell Carcinoma-Associated Antigen G250 Induces Specific Cellular Immune Responses," <u>Int. J. Cancer</u> , 59: 802-807 (1994)
	Uemura et al., "Anti-tumor effects of vaccination with internal image anti-idiotypic monoclonal antibodies," <u>Biotherapy</u> (Japan), 9(3): 294-295 (1995) (English Language Summary)
	Uemura et al., "Possible tools for active specific immunotherapy with anti-idiotypic antibodies in human renal cell carcinoma," <u>Biotherapy</u> (Japan), 10(3): 241-244 (1996) (English Language Summary)
	Uemura et al., "Expression of Tumor-Associated Antigen MN/G250 in Urologic Carcinoma: Potential Therapeutic Target," <u>Journal Urology</u> , 157 (4-Suppl.): 377 (April 16, 1997)
	Uemura et al., "MN Target Immunotherapy for Renal Cell Carcinoma," <u>J. Urology</u> , 159 (5 Suppl.): 187, Abstract No. 724 (1998)
EXAMINER	DATE CONSIDERED

 <p><b>INFORMATION DISCLOSURE STATEMENT</b></p>	ATTY. DOCKET NO. D-0021.502	SERIAL NO. 09/967,237
	APPLICANT Zavada et al.	
	FILING DATE September 27, 2001	GROUP

## OTHER DISCLOSURES

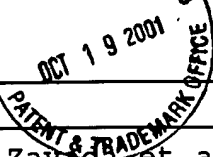
1	Van Dijk et al., "Induction of Tumor-Cell Lysis by Bi-Specific Monoclonal Antibodies Recognizing Renal-Cell Carcinoma and CD3 Antigen," <u>Int. J. Cancer</u> , 43: 344-349 (1989)
1	Van Dijk et al., "Therapeutic Effects of Monoclonal Antibody G250, Interferons and Tumor Necrosis Factor, In Mice with Renal-Cell Carcinoma Xenografts," <u>Int. J. Cancer</u> , 56: 262-268 (1994)
1	Vermylen et al., "Expression of the MN antigen as a biomarker of lung carcinoma and associated precancerous conditions," <u>Proceedings of the American Association for Cancer Research</u> , (Abstract #2280) (March 1998)
1	Vessella et al., "Monoclonal antibodies to human renal cell carcinoma: recognition of shared and restricted tissue antigens," <u>Cancer Res.</u> , 45(12, Pt. 1): 6131-6139 (1985)
1	Young and Davis, "Efficient Isolation of Genes by Using Antibody Probes," <u>PNAS (USA)</u> 80: 1194-1198 (March 1983)
1	Zavada, "The Pseudotypic Paradox," <u>J. gen. Virol.</u> , 63: 15-24 (1982)
1	Zavada and Zavadova, "A Transmissible Antigen Detected in Two Cell Lines Derived from Human Tumours," <u>J. gen. Virol.</u> , 24: 327-337 (1974)
1	Zavada and Zavadova, "An unusual transmissible agent -- MaTu," <u>Arch. Virol.</u> , 118: 189-197 (1991)
1	Zavada et al., "VSV Pseudotype Produced in Cell Line derived from Human Mammary Carcinoma," <u>Nature New Biology</u> , 240: 124-125 (November 22, 1972)
EXAMINER	DATE CONSIDERED

ATTY. DOCKET NO.  
D-0021.502SERIAL NO.  
09/967,237

## INFORMATION DISCLOSURE STATEMENT

APPLICANT  
Zavada et al.FILING DATE  
September 27, 2001

GROUP



## OTHER DISCLOSURES

Zavada et al., "Tumorigenicity-Related Expression of MaTu Proteins in HeLa x Fibroblast Hybrids," Abstract presented at the XIX Meeting of the European Tumor Virus Group (May 1-4, 1991)

Zavada et al., "A Presumed New Oncoprotein - MN - Used as Experimental Antitumor Vaccine," J. Cancer Res. Clin. Oncol., 119, (Suppl. 1) 2/24 (1993)

Zavada et al., "Expression of MaTu-MN Protein in Human Tumor Cultures and in Clinical Specimens," Int. J. Cancer, 54: 268-274 (1993)

Zavada et al., "MN - A Novel Type of Human Oncogene," Abstract submitted to EMBL Conference: Oncogenes & Growth Control, Heidelberg (21-24 April 1996)

Zavada et al., "A novel oncoprotein, MN, implicated in cervical carcinoma," Abstract submitted to ETVG Meeting, Innsbruck (March 1997)

Zavada et al., "Transient transformation of mammalian cells by MN protein, a tumor-associated cell adhesion molecule with carbonic anhydrase activity," International Journal of Oncology, 10: 857-863 (1997)

Zavadova et al., "Novel tumor-associated MN protein is a cell adhesion molecule," for conference on Molecular Genetics of Cancer, Oxford, September 1997

EXAMINER

DATE CONSIDERED